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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/711,855	04/16/01	KALATZ B	RDID0006US

EXAMINER	
SHEINBERG,M	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/711,855	Applicant(s) KALATZ ET AL.	
	Examiner Monika B. Sheinberg	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-10,12 and 32-37* is/are pending in the application.

4a) Of the above Claim(s) *11,13-31 and 38-45* is/are ~~withdrawn from consideration~~. Canceled.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1 sheet* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Election

Applicant's election without traverse of Group I, claims 1-10, 12, and 32-37, in Paper No. 6, filed on 2 July 2001, is acknowledged. The amendment filed on 2 July 2001, canceling all claims drawn to the non-elected invention (claims 13-31 and 38-45) and in addition claim 11 of the elected invention is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the ***first*** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, and 32-37, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

One skilled in the art would realize, in view of the Biochemistry textbook reference by McGilvery et al.(1983), that insulin and glucagon play a major roles in regulating the metabolism of glucose. The combined effects of the two hormones, glucagon and insulin, control the glucose concentrations within the body. However the instant application lacks any involvement or consideration of the effects of glucagon within the extrapolation of glucose concentrations. Due

to the lack of one of the two key hormones, glucagon, the extrapolated glucose concentration (G_p) is not enabled.

Claims 2-5, 12, 32, 34, and 35, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The instant application lacks any amount or direction as to the practice of determining useful values for the evaluation elements. Nowhere in the claims or the specification is there a clear and direct explanation as to how the stated elements are to be selected from a broad range of values available for election; for example, in the specification the empirical weighting factor, A, has a range from 0-100 minutes, not nowhere does the specification enable any process to

select 5 instead of 95 minutes. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of working examples in the specification, and the unpredictability of the selection of a functional value for the evaluation elements listed below, the specification, as filed is not enabling for the method of determining useful values for the evaluation elements as claimed. As such, claims drawn to the use of evaluation elements are not enabled.

1. D: the value determination of this "empirical weighting factor" is not enabled (claim 2);
2. SE: the measurement value determination of subjective term "sensitivity" is not enabled (claim 4);
3. E: "is a factor" is a non-enabled value due to R_{KH} and F not being enabled as shown below (claim 2);
4. X: the method of value determination where X "is unequal to zero" is not enabled' (claim 2);
5. R_{KH}: the carbohydrate reduction factor value determination is not enabled (claim 3);
6. F: the value determination of this "empirical factor" is not enabled (claim 3);
7. GB: this quantity is not enabled due to the lack of enablement of SE (see above) and C (see below) from which it is calculated (claim 4);
8. C: the value determination of this "empirical weighting factor" is not enabled (claim 4);
9. SG * A: this quantity is not enabled due to the lack of enablement of A (see below) from which it is calculated (claims 5 and 32);

10. A: the value determination of this "empirical weighting factor" is not enabled (claims 5 and 32); and
11. m: the value of *m* of the summation lacks any definition and thus is not enabled (claim 12).

The value determination is not disclosed in a manner that one skilled in the art would be enabled to determine without undue experimentation which value to utilized within the glucose concentration extrapolation.

Claims 1-10, 12, and 32-37, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific formulas per se for calculation of evaluation elements subject to the above rejections based on a lack of enablement, does not reasonably provide enablement for how each of these evaluation elements functions separately. The specification lacks a summary of exactly how these elements are independently functional and thus does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims. Subject to the above glucagon enablement issue and parameter enablement issue being resolved, the instantly enabled glucose concentration extrapolation requires the following elements to be evaluated only as listed below as a connected complete set:

1. G_p: formula of claim 2, line 3;
2. I_{wirk}: formula of claim 33, line 4;
3. KH_{wirk}: formula of claim 12, line 4;
4. E: formula of claim 3, line 1;

5. GB: formula of claim 4, line2; and

6. quantity SQ*A: claims 5 and 32, line 2.

Claim 1 must at least be limited to the exact combination of these factors. There is no instantly disclosed other way to calculate this extrapolation method and therefore these factors should be amended into claim 1. As such, claims drawn to the independent use of evaluation formulas are not enabled.

The following is a quotation of the ***second*** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, and 32, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5, and 32, are vague and indefinite in the manner that the term "contains" is used. It is unclear how the factor, X, can "contain" the quantity GB. It is doubtful that one value can "contain" another unless the GB quantity is utilized within a formula to calculate the quantity of X. The term "contains" is utilized in a likewise manner in claims 5 and 32, thus follows are also lack clarity.

Claims 2-5, 12, and 32-35, are rendered vague and indefinite due to the lack of clarity of the mode of calculation which is meant by the asterix in all the formulas within the claims. Is multiplication meant, or some other mathematical operation?

No claim is allowed.

Closure

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER

August 31, 2001

Monika B. Sheinberg
Patent Examiner
Art Unit 1631

MBS